K011839

510(k) SUMMARY

JAN 1 7 2002

Doxa Certex AB's DoxaDent™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Doxa Certex AB
Axel Johanssons
gata 4 – 6,
SE-75451 Uppsala, Sweden
Phone: +46-18-4782000
Facsimile: +46-18-4782071

Contact Person: Nils-Otto Ahnfelt

Date Prepared: June 12, 2001

Name of Device and Name/Address of Sponsor

DoxaDent™

Doxa Certex AB
Axel Johanssons
gata 4 – 6
SE-75451 Uppsala, Sweden

Common or Usual Name

DoxaDent Dental Ceramic

Classification Name

Tooth Shade Resin Materials

Predicate Devices

- Dentsply AP Dyract® Compomer dental composites
- Bisco, Inc.'s PYRAMID™, ADVENT™, and RENEW™ dental composites
- Coltène/Whaledent's Coltosol Temporary Endodontic Filling

Intended Use/Indications for Use

DoxaDent is a dental ceramic composed of calcium aluminate cement and oxides that is intended to restore carious lesions or structural defects in teeth. Specifically, DoxaDent is indicated for use as a restorative dental material for permanent application in the treatment of class I, II, and V cavities.

Technological Characteristics and Substantial Equivalence

DoxaDent™ is a dental ceramic composed of a calcium aluminate cement and oxides, *i.e.*, silica and zirconium oxide, and iron oxide colorants, as a filler material, in a blend of fine irregularly shaped particles ranging from 0.5 to 5 μm in diameter and microfine particles having a diameter of 0.02 to 0.2 μm. Trace concentrations of iron oxide additives (< 0.05% w/w) and alkali salt accelerators (LiCl, < 0.1% w/w) are included to provide for coloring and to control the rate of hydration, respectively.

DoxaDent™ is substantially equivalent to a combination of Dentsply AP Dyract® Compomer, Bisco, Inc.'s PYRAMID™, ADVENT™, and RENEW™ dental composites, as well as Coltène/Whaledent's Coltosol Temporary Endodontic Filling. Any minor difference do not raises any new issues of safety or effectiveness.

Performance Data

The following performance test were conducted by Doxa Certex AB on the DoxaDent™:

- Flexural properties
- Shade
- Color stability
- Radio-opacity
- Working and setting times
- Study on the marginal adaptation of DoxaDent™ in extracted teeth
- Microstructure of DoxaDent™
- Determination of compressive strength
- Some aspects of biocompatibility and chemical stability of a calcium-aluminate-hydrate-based dental restorative material, submitted for publication to the 2001 IADR meeting in Chiba, Japan

- Acid erosion by impinging jet technique according to EN 29917:1994/ISO 9917:1991 and Technical Corrigendum 1:1993 Dental water-based cements
- Dimensional stability
- Wear testing
- Leakage (Leaching) and pH
- Electrical pulp sensitivity test
- Hardness

In all instances, the DoxaDent™ functioned as intended and performance observed was as expected.

Clinical Data

DoxaCertex AB performed X-ray analysis of DoxaDent implants and evaluation of gingival reactions and plaque formation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 7 2002

Doxa Certex AB
C/O Mr. Jonathan S. Kahan
Hogan and Harton
555 13th Street Northwest
Washington, District of Columbia 20004-1109

Re: K011839
Trade/Device Name: DoxaDent™
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Materials
Regulatory Class: II
Product Code: EBF
Dated: October 31, 2001
Received: October 31, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011839

Device Name: DoxaDent™

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011839